Response Survey, with two more in development. FDA is now seeking OMB clearance to continue collecting this information. Participation in these surveys has been, and will continue to be, voluntary. This request covers Rapid Response Surveys for general type medical facilities and specialized medical facilities (those known for cardiac surgery, obstetric/gynecological services, pediatric services, etc.), and health professionals, but more typically risk managers working in medical facilities.

FDA currently uses the information gathered from these surveys to quickly obtain vital information from the appropriate clinical sources so that FDA may take appropriate public health or regulatory action. FDA projects 10 rapid response surveys per year with a sample of between 50 and 200 respondents per survey.

FDA originally estimated the burden of this collection to be 2 hours per survey. However, FDA is revising the estimated burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency of Respondent	Total Annual Responses	Hours per Responses	Total Hours
200	10 (maximum)	2,000	.5	1,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on the maximum sample size per questionnaire that FDA could analyze in a timely manner. The annual frequency of respondent was determined by the maximum number of questionnaires that will be sent to any individual respondent. Some respondents may be contacted only one time per year, while another respondent may be contacted several times— depending on the medical device under evaluation. Based on the questions developed for the one survey that has been conducted, and for the two under development, it is estimated, given the expected type of issues that will be addressed by the surveys, that at a maximum it will take 30 minutes for a respondent to gather the requested information and fill in the answers.

Dated: September 21, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01-24163 Filed 9-26-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01E-0098]

Determination of Regulatory Review Period for Purposes of Patent Extension; TNKase

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TNKase and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human biological product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets.ecomments.

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD-007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biological product TNKase (tenecteplase). TNKase is indicated for reduction of mortality associated with acute myocardial infarction (AMI). Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for TNKase (U.S. Patent No. 5,385,732) from Genetech, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 11, 2001, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of TNKase represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for TNKase is 1,990 days. Of this time, 1,741 days occurred during the testing phase of the regulatory review period, while 249 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: December 23, 1994. The applicant claims February 22, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
314.81(b)(2)(i)	100	1	100	8	800
314.81(b)(2)(vi)(c)	100	1	100	24	2,400
314.81(b)(2)(vii)	100	1	100	1.5	150
601.27(a)	2	1	3	48	144
601.27(b)	5	1	5	24	120
601.27(c)	3	1	4	8	32
601.28(a)	69	1	69	8	552
601.28(b)	69	1	69	24	1,656
601.28(c)	69	1	69	1.5	103.5
Total					17,215.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: September 21, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01-24162 Filed 9-26-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0399]

Agency Information Collection Activities; Proposed Collection; Comment Request; Rapid Response Surveys

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed continued collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Rapid Response Surveys to obtain data from health professionals and medical-device-user facilities when FDA must quickly determine whether or not a problem with a medical device impacts the public health.

DATES: Submit written and electronic comments on the collection of information by November 26, 2001.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Rapid Response Surveys (OMB Control Number 0910-0457)—Extension

Under section 519 of the Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360i), FDA is authorized to require manufacturers to report medical device related deaths, serious injuries, and malfunctions, and user facilities to report device-related deaths directly to FDA and to manufacturers, and to report serious injuries to the manufacturer. Section 522 of the act (21 U.S.C. 360l) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health, or gross deception of the consumer. Section 903(d)(2) of the act (21 U.S.C. 393(d)(2)) authorizes the Commissioner of Food and Drugs (the Commissioner) to implement general powers (including conducting research) to effectively carry out the mission of FDA. These sections of the act enable FDA to enhance consumer protection from risks associated with medical device usage that are not foreseen or apparent during the premarket notification and review process. FDA monitors medical product related postmarket adverse events via both the mandatory and voluntary MedWatch Reporting Systems using FDA form 3500 and 3500A (OMB control number 0910-0281).

FDA received a 1-year OMB approval on February 5, 2001, to implement Emergency Health Surveys (since that time, renamed "Rapid Response Surveys"), via a series of surveys, thus implementing section 705(b) of the act and the Commissioner's authority as specified in section 903(d)(2) of the act. To date, FDA has initiated one Rapid